SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND FRANKUM – POPEK, INC. d/b/a MEDICINE STORE

Come now Frankum - Popek, Inc. d/b/a Medicine Store ("Respondent" or "Medicine Store") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 004238, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

- 1. Petitioner, the Missouri Board of Pharmacy ("the Board"), is an agency of the State of Missouri created and established by Section 338.110, RSMo, for the purpose of administering and enforcing the provisions of Chapter 338, RSMo.
- 2. Respondent, Frankum Popek, Inc. d/b/a Medicine Store ("Medicine Store"), holds a pharmacy permit issued by the Board, Permit No. 004238, to operate a pharmacy at 1302 East Sunshine, Springfield, Missouri. Medicine Store's permit is, and was at all times relevant herein, current and active.

Theft of Controlled Substances

- 3. Hydrocodone / APAP, 7.5/ 650 is a combination drug product containing Hydrocodone which is codified as a Schedule III controlled substance pursuant to §195.017.6(4)(d) RSMo. (Supp.2008).
 - 4. On or about October 14, 2008, Medicine Store employees attempted to fill a

patient prescription for Hydrocodone / APAP, 7.5/ 650 when they noticed that the pharmacy's 500-count stock bottle of this drug was missing.

- 5. Medicine Store pharmacy is equipped with video surveillance.
- 6. Medicine Store staff reviewed the pharmacy's surveillance video and discovered that on October 11, 2008, pharmacy technician J.W. had placed the stock bottle of Hydrocodone / APAP, 7.5/650 into the trash and later escorted the trash to the dumpster.
- 7. On or about October 16, 2008, Gerald Popek also reviewed the pharmacy's video surveillance.
- 8. On or about October 17, 2008, Gerald Popek conducted an audit of Hydrocodone / APAP, 7.5/650 and confirmed a shortage of tablets.
- J.W. was terminated from his employment as a pharmacy technician at Medicine
 Store on October 18, 2008.
- 10. On October 23, 2008 Gerald Popek notified the Board that he had terminated pharmacy technician J.W. for alleged theft of controlled substances.
 - 11. The Board initiated an investigation on or about October 27, 2008.

Interview with J.W.

- 12. On December 7, 2008, Board Inspector George McConnell conducted an interview with J.W. after his termination from Medicine Store pharmacy.
- 13. J.W. admitted to Board Inspector McConnell that he had an addiction to Oxycodone/Hydrocodone.
- 14. J.W. admitted to Board Inspector McConnell that he stole approximately 200-250 tablets from the pharmacy prior to the October 2008 theft which led to his termination.

- 15. J.W. admitted to Inspector McConnell that he took 100-tablet stock bottles of various strengths from the Medicine Store pharmacy.
- 16. J.W. provided a written statement to Board Inspector McConnell dated December 7, 2008 which further detailed his addiction to oxycodone and acknowledges that he was fired from the Medicine Store pharmacy for stealing pills.

Loss of Controlled Substances

- 17. Gerald Popek conducted an inventory of Hydrocodone / APAP, 7.5/ 650 on October 17, 2008.
- 18. On October 23, 2008, Gerald Popek notified the Board and BNDD that a theft of controlled substances had occurred at the Medicine Store pharmacy.
- 19. Gerald Popek provided the Board with a faxed copy of a letter dated October 23, 2008 addressed to the Bureau of Narcotics and Dangerous Drugs ("BNDD"). Gerald Popek's October 23, 2008 letter to BNDD admits a shortage of 448 tablets of Hydrocodone/APAP 7.5/650 occurred at the Medicine Store while Gerald Popek was serving as Pharmacist-In-Charge ("PIC").
- 20. On October 23, 2008, Gerald Popek signed and faxed a Report of Loss or Theft Of Controlled Substances form to BNDD and the Board which reports a theft or loss of 448 tablets of Hydrocodone / APAP, 7.5/650.
- 21. On or about November 5, 2008, Board Inspector McConnell conducted a routine inspection at Medicine Store and continued his investigation of the reported theft of controlled substances from Medicine Store.
 - 22. During his inspection, Board Inspector McConnell conducted an audit of the

Medicine Store pharmacy's Hydrocodone and Alprazolam products ranging from January 23, 2007 through November 5, 2008.

23. The results of Board Inspector McConnell's audit show a loss of controlled substances as follows:

	Total	Total		Percent
Drug & Strength	Accountable for	Accounted for	Difference	Difference
Alprazolam 0.5 mg	66,350	66,474	124	0.2%
Alprazolam 1 mg	59,750	60,461	711	1.2%
Alprazolam 2 mg	8,700	8,485	-215	-2.5%
Hydrocodone/apap 7.5/650	37,400	37,968	568	1.5%
Hydrocodone/apap 10/650	22,900	22,798	-102	-0.4%
Hydrocodone/apap 10/325	123,500	108,153	-15,347	-12.4%
Hydrocodone/apap 5/500	63,400	64,137	737	1.2%
Hydrocodone/apap 7.5/500	12,500	12,589	89	0.7%

- 24. Medicine Store failed to provide adequate security in order to deter theft of drugs by Medicine Store personnel including, but not limited to pharmacy technician, J.W.
- 25. Medicine Store failed to keep an accurate inventory and/or accurate records of the pharmacy's stock of controlled substances including, but not limited to its stock of Hydrocodone / APAP, 7.5/ 650, Alprazolam 0.5 mg, Alprazolam 1 mg, Alprazolam 2 mg., Hydrocodone/APAP 10/650, Hydrocodone/APAP 10/325, Hydrocodone/APAP 5/500, and Hydrocodone/APAP 7.5/500.
- 26. Medicine Store failed to assure that the procedures in place at the Medicine Store pharmacy regarding the handling, dispensing and recordkeeping of controlled substances were in compliance with state and federal laws.
- 27. Medicine Store failed to ensure that appropriate policies and procedures were in place to prevent and/or deter J.W. and other pharmacy personnel from stealing controlled

substances from the Medicine Store pharmacy.

- 28. Medicine Store failed to insure the safety and integrity of all drugs located in the pharmacy.
- 29. Medicine Store's failure to maintain adequate security in order to deter theft of drugs is in violation of 20 CSR 2220.2-010(H) which states:
 - (H) Pharmacies must maintain adequate security in order to deter theft of drugs by personnel or the public. Sufficient alarm systems or locking mechanisms must be in place if the pharmacy is located in a facility into which the public has access and the pharmacy's hours of operation are different from those of the remainder of the facility.
- 30. Medicine Store's failure to have adequate controls in place to detect and prevent the diversion of controlled substances is in violation of 19 CSR 30-1.031 which states in part:
 - (1) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Department of Health shall use the security requirement set forth in 19 CSR 30-1.032.19 CSR 30-1.034 as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the Department of Health after evaluation of the overall security system and needs of the applicant or registrant.
 - (2) Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred to a different schedule, or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security controls shall be expanded accordingly.
- 31. Medicine Store's failure to secure and disperse controlled substances in such a manner as to obstruct theft or diversion by its employees and/or others is in violation of 19 CSR

30-1.034(1) which states:

- (1) Physical Security.
 - (A) Controlled substances listed in Schedules I and II shall be stored in a securely locked, substantially constructed cabinet.
 - (B) Controlled substances listed in Schedules III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse these substances throughout the stock of noncontrolled substances in such a manner as to obstruct theft or diversion of the controlled substances.

* * *

- 32. Medicine Store's failure to assure that adequate security and controls were in place to detect and prevent the diversion of controlled substances is in violation of 21 CFR 1301.71(a) which states:
 - (a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Sections 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in Sections 1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.
- 33. Medicine Store's failure to maintain adequate security controls to detect and prevent the diversion of controlled substances is in violation of 21 CFR 1301.75(b) which states:
 - (b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

Unlicensed Pharmacy Technician

- 34. J.W. was employed as a pharmacy technician at Medicine Store for approximately two (2) years prior to his termination of employment on October 18, 2008.
- 35. Gerald Popek, as PIC of Medicine Store, executed and submitted an Application for Registration As Pharmacy Technician on behalf of J.W. dated November 9, 2006.
- 36. The Board's records show that J.W. was granted a pharmacy technician's registration on June 7, 2007 which expired on May 31, 2008.
 - 37. J.W.'s employment from Medicine Store was terminated on October 18, 2008.
- 38. On October 23, 2008, Gerald Popek wrote to the Board and stated his belief that J.W.'s pharmacy technician registration was still in "application" status and requested that J.W.'s application be terminated immediately.
- 39. On October 23, 2008, Medicine Store wrote to the Bureau of Narcotics and Dangerous Drugs and admitted that J.W. was "employed as a pharmacy technician," and also stated his belief that J.W.'s registration "was still in application status with the Board of Pharmacy".
- 40. Medicine Store employed J.W. as a pharmacy technician for more than ninety (90) days prior to the issuance of a certificate of registration to J.W.
- 41. Medicine Store never secured a copy of J.W.'s pharmacy technician registration and failed to maintain a record of J.W.'s registration at the Medicine Store pharmacy.
 - 42. J.W.'s pharmacy technician registration expired on May 31, 2008.
- 43. Medicine Store employed J.W. as a pharmacy technician for four and one-half (4 ½) months after J.W.'s pharmacy technician registration expired.

- 44. Medicine Store allowed J.W. to work in the Medicine Store's prescription area without a valid pharmacy technician registration from the Board.
- 45. Medicine Store allowed J.W. to have independent access to legend drug stock on a routine basis at the Medicine Store pharmacy without a valid pharmacy technician registration from the Board.
- 46. Medicine Store's employment of J.W. as a pharmacy technician for more than ninety (90) days prior to June 7, 2007 and Medicine Store's employment of J.W. for approximately four and one half (4 ½) months after May 31, 2008 is in violation of 20 CSR 2220-2.700(1)(A) which states:
 - (A) No person shall assume the role of a pharmacy technician without first registering with the board in accordance with the requirements in section 338.013, RSMo and this rule. Nothing in this rule shall preclude the use of persons as pharmacy technicians on a temporary basis as long as the individual(s) is registered as or has applied to the board for registration as a technician in accordance with 338.013.1 and .2, RSMo.
- 47. Medicine Store's employment of J.W. as a pharmacy technician for more than ninety (90) days prior to June 7, 2007 and Medicine Store's employment of J.W. for approximately four and one half (4 ½) months after May 31, 2008 is in violation of Section 338.013, RSMo which states, in part:
 - (1) Any person desiring to assist a pharmacist in the practice of pharmacy as defined in this chapter shall apply to the board of pharmacy for registration as a pharmacy technician. Such applicant shall be, at a minimum, legal working age and shall forward to the board the appropriate fee and written application on a form provided by the board. Such registration shall be the sole authorization permitted to allow persons to assist licensed pharmacists in the practice of pharmacy as defined in this chapter.

(3) If an applicant has submitted the required fee and an application for registration to the board of pharmacy, the applicant for registration as a pharmacy technician may assist a licensed pharmacist in the practice of pharmacy as defined in this chapter for a period of up to ninety days prior to the issuance of a certificate of registration. The applicant shall keep a copy of the submitted application on the premises where the applicant is employed. When the board refuses to issue a certificate of registration as a pharmacy technician to an applicant, the applicant shall immediately cease assisting a licensed pharmacist in the practice of pharmacy.

* * *

(5) Every pharmacy technician who desires to continue to be registered as provided in this section shall, within thirty days before the registration expiration date, file an application for the renewal, accompanied by the fee prescribed by the board. No registration as provided in this section shall be valid if the registration has expired and has not been renewed as provided in this subsection.

JOINT CONCLUSIONS OF LAW

- 48. Cause exists to take disciplinary action against Medicine Store's permit under 20 CSR 2220-2.010(1)(O), which states:
 - (O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.
- 49. Cause exists for Petitioner to take disciplinary against Medicine Store's permit under Section 338.285, RSMo, which states:

The board is hereby authorized and empowered, when examination or inspection of a pharmacy shall disclose to the board

that the pharmacy is not being operated or conducted according to such legal rules and regulations and the laws of Missouri with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a permit to operate a pharmacy with conduct constituting grounds for discipline in accordance with section 338.055.

- 50. Cause exists for Petitioner to take disciplinary action against Respondent's permit under Section 338.055 RSMo, which states in relevant parts:
 - 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

- (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter.
- (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter;

* * *

(13) Violation of any professional trust or confidence;

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

- 1. Respondent's permit to operate a pharmacy shall be placed on PROBATION for a period of three (3) years. The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:
 - A. Respondent shall pay all required fees for permitting to the Board and shall renew its pharmacy permit prior to October 31 for each licensing year.
 - B. Respondent shall comply with all provisions of Chapter 338 and 195; all applicable federal and state drug laws, rules and regulations; and all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.
 - C. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by Respondent, and the individuals' current home addresses and telephone numbers.
 - D. If, after disciplinary sanctions have been imposed, Respondent fails to keep its Missouri pharmacy permit current, the period of unlicensed status shall not be

deemed or taken as any part of the time of discipline so imposed.

- E. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Order/Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.
 - F. Respondent shall not serve as an intern training facility for interns.
- G. Respondent shall select a Missouri-licensed pharmacist consultant for the purpose of reviewing and insuring all compliance measures are carried out in accordance with all applicable laws and regulations. Respondent shall submit documentation and credentials of its chosen consultant to the Board office for approval prior to the beginning date of probation. Said consultant shall submit a written plan to the Board office outlining what procedures or changes in operation will be implemented and on what time table is proposed for completion. The consultant shall then provide ongoing reports to the Board office attesting to the pharmacy's compliance or noting deficiencies for each visit made. The visits and initial report shall be provided within sixty (60) days of the beginning of probation. Visits to the pharmacy to assess compliance will be completed at a minimum of a six (6) month cycle and reports to the Board office will be provided once every six (6) months throughout the disciplinary period. The consultant shall be hired at Respondent's expense.
- H. Consultant shall perform an audit and reconciliation on all controlled substances on a semi-annual basis. The consultant shall report the results of each

reconciliation to the Board office.

- I. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.
- J. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Order/Agreement.
- K. The parties to this Order/Agreement understand that the Board of Pharmacy will maintain this Order/Agreement as an open record of the Board as provided in Chapters 324, 338 and 610, RSMo.
- 2. Upon the expiration of said discipline, Respondent's permit to operate a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.
- 3. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of

this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

- 4. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.
- 5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.
- 6. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this

Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

REQUESTS

DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT TO OPERATE A PHARMACY.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's permit and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's permit. Effective the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's permit, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement agreement goes into effect 15 days after the document is signed by the Board's Executive Director.

RESPONDENT

FRANKUM - POPEK, INC. d/b/a MEDICINE STORE

By:

Gerald Popek President

HUSCH BLACKWELL SANDERS,

LLP

By:

Thomas D. Vaughn **#**20554

235 East High Street

P. O. Box 1251

Jefferson City, MO 65102-1251

Telephone: 573/635-9118

Fax: 573/634-7854

Attorneys for Respondent

PETITIONER

MISSOURI BOARD OF

PHARMACY

By:

Kimberly Grinston

Executive Director

Date: 1/-4-09

NEWMAN, COMLEY & RUTH

P.C.

By:

Lanette R. Gooch

601 Monroe, Suite 301

P.O. Box 537

Jefferson City, MO 65102-0537

Telephone: 573/634-2266

Fax: 573/636-3306

Attorneys for Petitioner